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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,791	11/29/2001	Geert Maertens	2551-68	9146

23117 7590 06/30/2004

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EXAMINER	
MOSHER, MARY	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,791	MAERTENS ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/16/02, 8/29/03,* .
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of group I in Paper No. 18 is acknowledged. The traversal is on the ground(s) that groups I and II share a common classification. This is not found persuasive because the E1 and E2 proteins require burdensome divergent search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-39 have been examined to the extent that they read upon the elected E1 protein species. Claim 15 is generic.

Specification

The disclosure is objected to because of the following informalities: page 85 contains sequence recitations without the required SEQ ID numbers.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 15-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16-17 are drawn to "a prophylactic HCV vaccine composition" and claims 18-19 are drawn to "a prophylactic HCV composition." Claims 16 and 18 recited exactly the ingredients in the same "prophylactically effective amounts;" similarly, claims 17 and 19 recite exactly the same ingredients and exactly the same amounts. Stedman's Medical Dictionary (27th edition) defines a vaccines as a "preparation intended for active

immunologic prophylaxis"; "prophylaxis" in turn is defined as "Prevention of disease or of a process that can lead to disease." So according to the ordinary usage of the terms, a "prophylactic composition" and "a vaccine composition" are the same thing. If some difference is intended between "a prophylactic composition" and "a prophylactic vaccine composition," it is not clear what the difference is, and the intended scope of these claims is not clear. Furthermore, it is noted that the specification defines "vaccine" on page 9 as "capable of eliciting protection against HCV, whether partial or complete." This is at variance with the ordinary meaning of the term. Furthermore, it is not clear how applicant intends to define and measure "partial protection". For these reasons, it is not clear what is included and what is excluded from a "prophylactic HCV vaccine composition." Since this language is included in claim 15, the intended scope of claim 15 is also seen as unclear.

In addition, claims 16-19 involve a "single or specific oligomeric envelope E1 protein or a part thereof." Page 6 defines "single or specific oligomeric E1 protein" as single monomeric proteins or oligomeric proteins which are not aggregates." It is not clear if the "single or specific" limitation applies to the recited "part thereof" in the claims.

Claims 16-19 are also incomplete for omitting essential elements. See MPEP § 2172.01. The specification states on page 9-10 that "the essence of these 'single or specific oligomeric' envelope proteins of the invention is that they are free from contaminating proteins and that they are not disulfide bond liked with contaminants." This "essence of the invention" is not clear in the invention as claimed.

Claims 27-29, 31, 33, 35, 36 are confusing. The claims recite "inducing an immune response" or "preventing evolution to chronic infection," but require use of a composition that contains components in amounts effective to prevent disease ("prophylactic HCV composition" in the parent claims). Therefore the scope of the methods conflict with the scope of the compositions used in the methods.

Claim 20 is indefinite because it recites "said E1 protein is E1s", but neither the claims or the specification defines "E1s". Therefore it is not clear what is required by this claim.

These problems affect the dependent claims.

Claims 15-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 16-19 require "a prophylactically effective amount" of a "single or specific oligomeric envelope E1 protein". Claim 15 is still more broadly drawn to any prophylactic HCV vaccine composition. Forns et al (Journal of Hepatology 37:684-695, 2003) is cited as evidence that prophylactic vaccines against hepatitis C virus were regarded as a challenge at least a year after the invention was made, indicating that those skilled in the art would not accept without question an unsupported assertion regarding prevention of disease. The specification does not teach any composition that has been shown to prevent disease, so the specification does not provide guidance on what amount of what material is prophlyactically effective. The specification does

provide a working example (Ex. 15) of a useful immunogenic composition which is able to prevent chronic infection of an animal after immunization, but even this example only describes the material used in this example by use of improper incorporation by reference to several extraneous documents. Therefore it is not even clear from the specification what materials were used in the only successful body-treating method disclosed in the specification. Considering the scope of the claims, the state of the art, the limited guidance in the specification, and the incomplete disclosure in the only working example, it is concluded that undue experimentation would be required to make and use the claimed vaccines and methods.

In addition, since claim 20 requires a product that is not even defined by the specification, it is concluded that undue experimentation would be required to make and use this composition.

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is requested to point to support in the specification as filed for "viral-like particles" of E1. It is noted that Example 15 mentions E1 particles, but the examiner was unable to find any description of E1 particles that resembled HCV virus. This is a "new matter" rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15 and 30 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Houghton et al (Prospects for Prophylactic and Therapeutic Hepatitis C Vaccines, Princess Takamatsu Symp. 25:237-243,1995, cited in 8/29/03 IDS). See page 238.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-26, 38-39 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Liang et al WO 98/21338 (in 4/16/2002 IDS). These claims are drawn to compositions. Liang teaches an immunogenic composition comprising HCV virus-like particles comprising the E1 protein, see e.g. claim 12 and Example 7. Since the virus-like particles are not aggregates, they meet the requirement for a "specific oligomeric envelope E1 protein" as defined on page 6 of the instant specification. The Liang composition also comprises

PBS, which is a pharmaceutically acceptable carrier. As discussed above, it is not clear from the instant specification what amount of E1 constitutes a prophylactically effective dose. However, the instant specification teaches 50 ug of E1 particles per dose in example 15, and Liang teaches a composition which is immunogenic and contains approximately 200 ug of the particles per dose. Therefore, the composition by Liang appears to contain at least as much E1 as applicant's working example, and therefore appears at least as likely to be prophylactically effective as any composition taught in the instant specification. See In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977):

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on `inherency' under 35 U.S.C. § 102, on `prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted].

Claims 5-39 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Depla et al WO 99/67285 (in 3/16/2004 IDS). Depla teaches compositions comprising the same ingredients as the instant claims, and teaches "use of an oligomeric particle as defined herein for prophylactically inducing immunity against HCV." See pages 20-21, for example, and Examples 1-4. The reference therefore teaches each and every element of the claimed invention. Depla does not contain a working example demonstrating administration to an uninfected subject. However, Depla clearly at least explicitly suggests the claimed

prophylactic products and methods, and it would have been within the ordinary skill of the art to carry out the explicit suggestions. Considering the teachings of effective treatment of a previously infected animal in Example 4, one would have had a reasonable expectation of success in inducing a useful immune response in a host before infection. The invention as a whole is therefore prima facie obvious, if not anticipated by the reference.

Claims 5-39 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No. 6,635,257, for essentially the same reasons as the rejection over its international equivalent Depla et al WO 99/67285.

The applied reference has a common inventor and a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection based on 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 15-26, 38, 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16, 19, 21 of U.S. Patent No. 6,635,257. Although the conflicting claims are not identical, they are not patentably distinct from each other because, even though the patent claims do not state the same intended use, the patented compositions contain the same ingredients as the instant claimed compositions.

Claims 15-26, 38-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-26, 41-42 of copending Application No.09/995,860. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to compositions, and differ only in the intended use. Since the compositions require identical ingredients, and the specification does not teach distinct and nonoverlapping effective amounts for prophylaxis versus therapy, the compositions appear to be the same, despite the difference in intended use.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6/27/04

MARY E. MOSHER
PRIMARY EXAMINER
GROUP ~~1800~~ 1600